

PATENT
Attorney Docket No. 09605.0045-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Maria PRAT QUINONES) Group Art Unit: 1625
Patent No.: 7,488,735 B2) Examiner: Niloofar RAHMANI
Issued: February 10, 2009) Confirmation No.: 5815
For: QUINUCLIDINE AMIDE)
DERIVATIVES)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**PETITION TO THE DIRECTOR UNDER 37 C.F.R. § 1.181 REQUESTING REVIEW OF
THE DISMISSAL OF PATENTEE'S APPLICATION FOR PATENT TERM
ADJUSTMENT - POST GRANT**

In accordance with 37 C.F.R. § 1.181(a)(3), Patentee hereby petitions the Director of the Patent and Trademark Office ("PTO") for review of the Decision on the Application for Patent Term Adjustment ("Decision") mailed on December 16, 2009. This petition is based partially on the *Wyeth* decision (*Wyeth . Kappos*, No. 2009-1120 (Fed. Cir. Jan 7, 2010)), and partially on a discrepancy on the Patent Term Adjustment ("PTA") based on the commencement date of the instant application.

**Patentee's Previous Petition under 37 C.F.R. §1.705(d) and Revised PTA
Determination Based on the Office's New Interpretation of 37 C.F.R. § 1.703(b)**

The United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,488,735 B2 ("the '735 patent") on February 10, 2009, with a PTA of 387 days. On March 24, 2009, Patentee filed an Application for Patent Term Adjustment - Post Grant

("Petition") requesting a total PTA of 580 days pursuant to the decision in *Wyeth*.

Dudas, 580 F.Supp.2d 138 (D.D.C. 2008).

In the Petition, Patentee calculated the total Patent Term Adjustment ("PTA") of 580 due to the period of delay under 37 C.F.R. §1.702(b) ("Three Year Pendency Provision") based, *inter alia*, on the Office's previous interpretation of the meaning of the date "the national stage commenced under 35 U.S.C. § 371(b) or (f) in an international application" recited in 37 C.F.R. § 1.703(b). According to previous Office practice, this date was taken to be as the date the requirements of Section 371 were fulfilled (August 1, 2005, in the present case). As now acknowledged implicitly by the Office, the date the national stage commenced under Section 371 is the day after the expiration of the 30 months from the priority date of the application. Decision at p. 2, ¶ 1. Specifically, the Office found the relevant dates to be January 3, 2005 (i.e., 30 months and one day after the July 2, 2002, priority filing date) and January 3, 2008 (i.e., three years from the national stage commencement date). Patentee agrees with the Office's current determination of the relevant day as well as the relevant ending date being the date of patent issuance (i.e., February 10, 2009). Based on these dates, Patentee calculates the delay under the Three Year Pendency Provision to be 404 days (i.e., number of days from January 3, 2008, to February 10, 2009). However, despite using the same dates, the Office calculates the delay to be 405 days. Decision at p. 2, ¶ 2. If after recalculating this value the Office determines that the PTO delay due to the three-year pendency rule is indeed 405 days, then Patentee will accept the Office's value of 405 days.

In the Petition, patentee agreed with the Office's determination of 416 day delay by the Patent Office for issuing a first Office Action more than fourteen months after the filing date of the application and a 29 day delay by applicant. The Patentee also agrees that there was no delay by the PTO in issuing the patent.

Because there is no overlap between the two periods of prosecution delay and the delay base on three year pendency, Patentee's revised PTA calculation is a total of 791 days (i.e., 416 days due to prosecution delay plus 404 days of delay base on three year pendency rule, minus 29 days of applicant delay).

Office's PTA Determination in the Decision

In dismissing Patentee's Petition, the Decision states that the period of adjustment under 35 C.F.R. § 1.702 in the instant case should be 387 days. Decision at p. 3, ¶ 6. Specifically, the Decision finds 405 days of Office delay under the Three Year Pendency Provision as well as 416 days of examination delay and 29 days of applicant delays. *Id.* The Decision states that the 405-day period under 35 C.F.R. § 1.702(b) overlaps with the 416 days under 37 C.F.R §§ 1.702(a)(1) and (a)(2) such that 416 days are the "actual number of days issuance of the patent was delayed." *Id.* at p. 3, ¶ 5. Accordingly, the Decision dismissed Patentee's Petition.

Statement of Facts

Based on the statements in the Decision, Patentee understands that Patentee and the Office agree on the following facts:

- a) the Office's examination delay was 416 days;
- b) applicant delay was 29 days,

- c) there was a delay based on the Three Year Pendency Provision, although the Office's calculation for this value is 405 days, whereas Patentee calculates this value at 404 days.

Issue to be Decided in the instant Response

At issue in this petition is whether the period of PTO examination delay in the instant application ("A delays," 416 days in this case) should be added to the PTO day under the Three Year Pendency Provision ("B delays," 404 days in this case) in order to obtain the total PTO delay (total delay, 820 days in this case). There is no dispute that the Patentee delay (29 days in this case) should be subtracted from the total PTO delay to arrive at the final value of the PTA.

Patentee argues that in view of the Federal Circuit's *Wyeth* decision, the 416 days in A delays should be added to the 404 days of B delays because they do not overlap (i.e., they did not occur on the same calendar days). According to the Office's interpretation in the Decision, there is an overlap of 404 days. Decision at p. 3, ¶ 2.

Arguments in Support of Patentee's Response

1. *The PTO's interpretation of 35 U.S.C. § 154(b) has been found to be improper by the Federal Circuit*

The decision in *Wyeth* clearly stated that the method used by the Office to calculate PTA by considering that A delays overlap with B delays and that Patentees only receive the greater of the two delays was inconsistent with 35 U.S.C. § 154(b)(1)(B). *Wyeth*, Slip Op. at 13. Applying the *Wyeth* decision to the instant case, the 404 days of PTO delay under the three-year pendency rule provided by 35 U.S.C. § 154(b)(1)(B) should be counted in addition to the PTO examination delay of 416 days

under 35 U.S.C. § 154(b)(1)(A) offset by 29 days of applicant's delay. Thus, the total of PTA for the '735 patent based on delay is 791 days.

The PTO's argument in the Decision indicated that Patentee's calculation of the period of overlap was inconsistent with the PTO's interpretation of 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f). See Decision at p. 3, ¶ 2. More particularly, the PTO asserted that the entire period of PTO delay under the Three Year Pendency Provision overlaps with the delay provided by 35 U.S.C. § 154(b)(1)(A) and 35 U.S.C. § 154(b)(1)(B) under 35 U.S.C. § 154(b)(2)(A). *Id.*, ¶ 5. Respectfully, the Federal Circuit has explicitly indicated that such a position is incorrect. *Wyeth*, Slip Op. at 13.

2. *The Office has a duty under 35 U.S.C. § 2(b)(2)(a), to establish regulations "not inconsistent with the law."*

Under 35 U.S.C. § 2(b)(2)(a), the PTO has a duty to establish regulations "not inconsistent with the law." In *Wyeth*, the Federal Circuit explained the proper construction of the provisions of 35 U.S.C. § 154(b) for determining PTA. *Wyeth*, Slip Op. at 8. Thus, Patentee requests that the PTO implement the Federal Circuit's decision regarding the proper statutory interpretation in order to be consistent with the current state of the law.

In accordance with *Wyeth*, the PTA for the '212 patent is 264 days, as set forth above.

Request for Relief

Patentee respectfully requests that the Office grant a total Patent Term Adjustment of 791 days to the '735 patent based on the arguments presented above.

However, if the Office's determination of 405 days due to the three-year pendency rule is correct, then the total PTA available to this patent should be 792 days.

If there are any fees due in connection with the filing of this request, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 12, 2010

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